

Application No. 10/084,545
Docket No. AD6799 US NA

REMARKS

As a preliminary matter, Applicants acknowledge the Examiner's detailed consideration of the Amendment dated June 30, 2003. The withdrawal of the objections as to the oath/declaration and the Abstract, and of all but one of the rejections under 35 U.S.C. § 112, is also acknowledged.

Objection

At the Examiner's instance, Applicants are amending the Abstract of the disclosure to eliminate the phrase "This invention pertains to". Applicants note in passing that the guidelines articulated in M.P.E.P. § 608.01 are phrased permissively; nevertheless, Applicants willingly comply with the Examiner's preference in this matter. Applicants therefore respectfully request that this objection be withdrawn upon reconsideration.

Rejections under 35 U.S.C. § 112

Applicants are presenting amendments to further clarify the antecedent basis of the phrase "the segmented polyurethanes" in claim 15.

Applicants are also presenting amendments to claims 32 and 33 that further clarify these claims. A basis for these amendments may be found in the specification on page 4 at lines 12 to 14, and in the claims as originally filed, for example.

Finally, an amendment that rectifies an apparent typographical error in claim 17 is presented.

Applicants believe that these amendments are purely formal and do not change the scope of the claims as originally presented. In light of these amendments, Applicants respectfully request that the rejection of claims 15 and 33 under 35 U.S.C. § 112 be withdrawn upon reconsideration.

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Rejections under 35 U.S.C. § 103

The Official Action dated September 23, 2003, has repeated the rejection of claims 1 to 9, 11 to 14, and 17 as obvious over U.S. Patent No. 4,637,396 issued to Cook (hereinafter "Cook") in light of U.S. Patent No. 3,981,415 issued to Fowler *et al.* (hereinafter "Fowler"). Also repeated are the rejection of claim 10 as obvious over Cook and Fowler in view of U.S. Patent No. 5,741,325 issued to Chaikof *et al.* (hereinafter "Chaikof"), the rejection of claim 15 as obvious over Cook and Fowler in view of U.S. Patent No. 4,704,130 issued to Gilding *et al.* (hereinafter "Gilding"), and the rejection of claims 32 to 34 as obvious over Cook and Fowler in view of U.S. Patent No. 6,159,238 issued to Killion *et al.* (hereinafter "Killion").

The Official Action also rejects claim 16 under 35 U.S.C. § 103 as obvious over Cook and Fowler in view of U.S. Patent No. 4,998,421 issued to Zafiroglu (hereinafter "Zafiroglu"). Finally, claim 35 is rejected as obvious over Cook and Fowler in view of Killion. These are the sole reasons presented in the Official Action dated September 23, 2003, why the present application has not been allowed.

Applicants respectfully request that these rejections be withdrawn upon reconsideration in light of the reasoning below.

First, each of the rejections under 35 U.S.C. § 103 is based on the combination of Cook and Fowler. Applicants have discussed Cook in combination with Fowler and further in view of each of the secondary cited references (Chaikof, Killion, Gilding and Zafiroglu) at length in the Amendment dated June 30, 2003. In addition, Applicants have considered the Examiner's detailed responses to this discussion.

Briefly, Applicants respectfully reiterate that the combined disclosures of Cook and Fowler do not teach or suggest every limitation of Applicants' claimed invention. For example, Cook does not describe a balloon catheter cover, but rather a reinforcing fabric that is internal to the balloon

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structure. See, e.g., Cook at col. 2, ll. 38 – 43. Nor does Cook teach or suggest elastic circumferential fibers and less elastic longitudinal fibers.

Fowler has been cited to support the proposition that a fabric structure of interconnected circumferential and longitudinal yarns is known in the art. Applicants respectfully renew their objection to the citation of Fowler, which is drawn from a non-analogous art. It is well-established that a reference pertains to a non-analogous art if "the reference was not within the field of applicant's endeavor, and was not reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992), *quoted in* M.P.E.P. § 2141.01(a). Applicants once more respectfully submit that one seeking to improve the performance of balloon catheters that are commonly used in cardiac surgery would simply not consider the art of fluid dispensing containers to be reasonably pertinent. Applicants note that Fowler contains no teaching or suggestion regarding balloon catheters, and that the structural adaptations required to transform a fluid dispensing container liner into an operational balloon catheter would be more than trivial.

Moreover, combining Cook and Fowler renders the balloon catheter in Cook unfit for its intended purpose, and therefore there is no motivation to combine these references. Specifically, Cook requires that the elastomer and hard fibers be parallel to each other (col. 3, ll. 10 – 17), that the fabric be a loosely-knitted "loopy" structure (col. 3, ll. 23 – 45), and that the fabric be capable of expanding three-dimensionally (col. 3, ll. 51 – 53). Using the fabric described in Fowler would destroy all of these requirements – the elastomer and hard fibers would not be parallel to each other, the fabric would not be loosely knit or "loopy", and the fabric would not be capable of expanding three-dimensionally.

Accordingly, Applicants respectfully request that the sole rejection of Claim 1, which is for obviousness over Cook and Fowler, be withdrawn upon reconsideration.

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Applicants note that all of the pending claims are directed to "a balloon catheter cover." Nevertheless, because the Official Action of September 23, 2003, takes the position that "the limitation on which Applicant relies (i.e. "balloon cover") is not stated in the claims" (Official Action at page 12, first full paragraph) and that "the tubular elastic structure (item 23) of Cook is a balloon catheter cover because it covers the inner layer of (item 22) of the balloon (item 12)" (*id.*), Applicants are presenting an amendment to claim 1 that is intended to further clarify the substance of the invention. The amendment to claim 1 addresses the ambiguity asserted in the Official Action by including a specific recitation, in the body of the claim, that the tubular elastic fabric structure is for covering the outer surface of a balloon catheter.

A basis for the amendment to claim 1 may be found in the specification, for example, on page 5 at lines 1 to 15, on page 6 at lines 21 to 38, on page 8 at lines 29 to 35, on page 10 at lines 26 to 34, and in Figures 1 and 5 to 9 and their accompanying text. Applicants believe that this amendment is purely formal and, accordingly, does not affect the scope of the claims. Further, it is apparent that Applicants have not made this amendment for reasons related to patentability.

Claims 2 through 18 and 32 through 35 are also rejected under 35 U.S.C. § 103. Each rejection relies on Cook and Fowler in view of one or more secondary references. Each of claims 2 through 18 and 32 through 35 depends, directly or indirectly, from claim 1. Therefore, by statute, claims 2 through 18 and 32 through 35 include every element of independent claim 1. As Applicants have set forth in detail above, the Cook and Fowler references do not teach or suggest every limitation of claim 1. It follows by logic that Cook and Fowler also do not teach or suggest every limitation of the dependent claims. For this reason, Applicants respectfully submit that the dependent claims are also not obvious. The above logic holds regardless of whether secondary references are asserted to show optional features of the invention appearing in the dependent claims.

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In summary, Applicants respectfully submit that the Official Action dated September 23, 2003, has not set forth a *prima facie* case for the obviousness of the claimed invention. In the alternative, Applicants respectfully submit that the above reasoning is sufficient to overcome a *prima facie* case for the obviousness of the claims (as amended herein to further improve their clarity) based on the combined disclosures of Cook and Fowler and optionally in view of Chaikof, Killion, Gilding or Zafiroglu. Accordingly, Applicants respectfully request that the rejections of claims 1 through 18 and 32 through 35 be withdrawn upon reconsideration.

Restriction Requirement

Claims 18 through 31 are currently withdrawn from examination as the result of a restriction requirement, which has been made final in the Official Action dated September 23, 2003. Applicants respectfully repeat their traversal of this restriction requirement. Claims 18 through 31 depend directly or indirectly from claim 1. First, the groups into which the claims have been restricted are related as product and process. These groups are therefore clearly linked. Second, the examination of claims directed to the balloon catheter covers of Applicants' invention will be substantially coextensive with the examination of claims directed to methods of making the balloon catheter covers. Therefore, the additional burden associated with the examination of claims 18 through 31 will not be serious. For these reasons, Applicants respectfully request that the restriction requirement be withdrawn upon reconsideration, and that all of the claims be examined together.

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Conclusion

In view of the above remarks and amendments, it is felt that all claims are now in condition for allowance and such action is requested. Should the Examiner believe that an interview or other action in Applicants' behalf would expedite prosecution of the application, the Examiner is urged to contact Applicants' attorney by telephone at (302) 992-3219.

Respectfully submitted,



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